510(k) SUMMARY

iFuse Implant System®

510(k) Owner's Name, Address, and Telephone Number
SI-BONE, Inc.
3055 Olin Avenue, Suite 2200
San Jose, CA 95128
(408) 207-0700

Contact Person
Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
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OCT 16 2013

Date Prepared: October 4, 2013

Trade Name of Device: iFuse Implant System®

Common or Usual Name: Orthopedic Rod

Classification Name:
21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener; Product Code OUR

Predicate Devices:
iFuse Implant System® by SI-BONE, Inc. (K080398, K092375, K110838, K122074, K123850)
Pioneer Cannulated Screw System by Pioneer Surgical Technology (K102903)

Intended Use
The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Device Description
The iFuse Implant System® consists of porous plasma spray coated titanium implants and associated surgical instruments. The iFuse Implant lengths range from 30-90mm with a diameter of 4-7 mm. The fusion rods are implanted using instrumentation similar to that previously described in K080398, K092375, K110838, K122074 and K123850.

Technological Characteristics
The iFuse Implant System® consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create fixation/stabilization and

fusion. There are no changes to the technological characteristics of the predicate device that are the subject of this 510(k).

Performance Data

Magnetic resonance (MR) imaging testing was performed to assess the compatibility and safety under typical MR conditions following aspects of ASTM F2052-06, ASTM F2182-11A and ASTM F2119-07. The iFuse Implant is MR conditional and labeled in compliance with ASTM F2503-08.

Substantial Equivalence

The iFuse Implant System has the same intended use, indications for use, and technological characteristics as the predicate device. Thus, the iFuse Implant System is substantially equivalent to the predicate device.

Further, the proposed longer device length is substantially equivalent to the Pioneer Cannulated Screw System manufactured by Pioneer Surgical Technology (Class II, Product Codes HWC, OUR; 21 CFR 888.3040).

Conclusions

The iFuse Implant System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

SI-BONE, Incorporated
% Ms. Cindy Domecus
Domecus Consulting Services, LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K131405
Trade/Device Name: SI-BONE iFuse Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: September 18, 2013
Received: September 19, 2013

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131405 (pg 1/1)

Device Name: SI-BONE iFuse Implant System

Indications for Use:

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices